

REMARKS

Claim 6 has been cancelled. Claims 1, 3, 4, 5, and 12 have been amended. New claim 13 is added. Claims 1-5 and 7-13 are now pending in this application. Claim 12 is withdrawn from consideration. Rejoinder of claim 12 is respectfully requested.

Support for the amendments is found in the existing claims and the specification. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Claim objection

Claim 5 has been objected to for not ending in a period. With this amendment, a period has been added to claim 5. Withdrawal of the objection is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to “wherein the organic compound is immobilized on the core particle by a chemical bond” to clarify that the organic compound is immobilized on the core particle.

Claim 5 has been amended to depend from claim 4. Claim 4 recites that “the base particles have a spherical or substantially spherical shape” consistent with the diameter recited in claim 5.

Claim 1 has been amended to clarify that there are multiple base particles, consistent with claim 5.

In view of Applicants’ amendments and remarks, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 1 and 4-11 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Takenishi, et al. (US 6,017,742).

Takenishi, et al. disclose a carbodiimide containing polymer, supported on a carrier, reacting with a biologically active substance via a carbodiimide group on the carrier (see col. 2,

lines 50-56). Takenishi, et al. teach supporting the carbodiimide compound on the carrier by “spraying, immersion, brushing, stamping, vapor deposition, coating with a film coater, or the like” (col. 5, lines 39-40). In the Examples of Takenishi, et al., wells (carrier) are coated with a carbodiimide solution (col. 8, lines 31-33).

In contrast, in the presently claimed invention, pre-treatment is performed in the production of the particle so that “the organic compound is immobilized on the core particle by a chemical bond” (Claim 1). That is, there is a chemical bond between the carrier and the organic compound which differs from the teaching of Takenishi, et al.

As taught in the specification at page 8, paragraph 3, for example, the core particle contains a compound (“B”) that has a functional group that can bond to the organic compound (“A”) by copolymerizing or mixing. See also, Production Examples 1 & 2, page 36, last paragraph to page 37 paragraph 1 and page 37, last paragraph. As a result of the pre-treatment, a chemical bond is generated between the core particle and the organic compound.

In contrast, Takenishi, et al. do not teach a pretreatment of the core particle to add a functional group that can bond to the organic compound. No chemical bond has been generated between the carrier and the carbodiimide in Takenishi, et al. Accordingly, Takenishi, et al. do not teach “wherein the organic compound is immobilized on the core particle by a chemical bond” (claim 1) as claimed by Applicants.

In the production example 5 of the present specification (pages 43-44 of the present specification) a process is followed similar to the teaching of Takenishi, et al. for comparative purposes. As can be seen by Table 3, the particles of Examples 1-4, prepared according to the claimed invention, compare favorably with the method of Production Example 5. The base particles produced according to the method similar to Takenishi, et al., were only partially monodispersed while the particles prepared according to the claimed invention were fully monodispersed. This feature is specifically recited in new claim 13.

In view of Applicants’ amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 1-6 and 8-10 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Sutton, et al. (US 5,955,108).

Sutton, et al. teach a sterile powder comprising microparticles. The microparticles comprise a crosslinked shell material selected from amino acid, a polyamino-acid and a polypeptide (see claim 1). The crosslinked material (the amino acid, polyamino-acid, or polypeptide “shell”) has free functional groups. The making of these microparticles is described in Example 1, using HSA as the polypeptide material for the shell. These shells are formed by heating to promote crosslinking of some of the amino acids in the HSA structure (col. 7, lines 14-19). Free thiol analysis, and peptide analysis were carried out and showed that the microcapsules did not differ significantly from albumin. These microcapsules do not have an organic compound immobilized on them as in Applicants’ claims.

Additives can be included in the microcapsules but these additives are incorporated into the matrix (Example 2), not chemically bound as in Applicants’ claimed invention.

Examples 5-8 teach derivatization of the microcapsules with methotrexate (Example 5), doxorubicin (Example 6), 5-fluor-2'-deoxyuridine (Example 7) and naproxen (Example 8). In each case, a carbodiimide is included in the reaction mix. However, in contrast to Applicants’ claimed invention, the carbodiimide is not chemically bound to the microparticle. Rather the carbodiimide is used to activate the active agent or biologically material to allow a condensation reaction to occur between the microparticle and the material. This is explained in col. 13, line 15-16, for example, which states that “[t]he EDC “activates” exposed carboxyl residues on the HSAMS, allowing covalent binding of Dox amino sugar”. This is different from Applicants’ claimed invention in which functional groups, such as carbodiimide groups, are attached directly to the core particle.

To further clarify Applicants’ invention and further distinguish the claimed invention from Sutton, et al. claim 6 has been incorporated into claim 1.

In view of Applicants’ amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

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application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee. Application entry in **BOLD** is the present application.

| Serial Number | Title | Filed |
|------------------|---|--------------------|
| 10/501691 | METHOD FOR IMMOBILIZING BIOMOLECULE ON CARRIER | 16-Jul-2004 |
| 10/535582 | METHOD OF IMMOBILIZING BIOMOLECULE TO METALLIC CARRIER | 18-May-2005 |
| 10/553092 | BIOLOGICALLY ACTIVE SUBSTANCE-IMMOBILIZED DEVICE | 13-Oct-2005 |
| 10/591720 | IMMOBILIZED BIOMOLECULE AND METHOD OF DETECTING SUBSTANCE CAPABLE OF INTERACTING WITH BIOMOLECULE | 05-Sep-2006 |
| 11/592900 | TIP FOR BIOMOLECULAR REACTION | 03-Nov-2006 |

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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